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Filing Date	Jul 26, 2001
First Named Inventor	Friddle, Carl Johan
Art Unit	1646
Examiner Name	J. Ulm
Total Number of Pages in This Submission: 17	Attorney Docket Number: LEX-0206-USA

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Firm or Individual	Lexicon Genetics Incorporated Lance K. Ishimoto Reg. No. 41,866
Signature	Lance K. Ishimoto by David W. Hibler DAVID W. HIBLER REG. NO. 41,071
Date	May 25, 2004

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AF/1646
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Reply Brief

Applicant(s)	Friddle et al.
Application #	09/916,122
Date Filed	July 26, 2001
Title	Novel Human 7TM Protein and Polynucleotides Encoding The Same
Attorney Docket #	LEX-0206-USA
Group Art Unit	1646
Examiner	J. Ulm

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Filed in Triplicate

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Friddle *et al.*		
Serial No.:	09/916,122	Group Art Unit:	1646
Filed:	07/26/2001	Examiner:	J. Ulm
For:	Novel Human 7TM Protein and Polynucleotides Encoding the Same	Attorney Docket No.:	LEX-0206-USA

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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REPLY BRIEF

Sir:

Appellants hereby submit an original and two copies of this Reply Brief to the Board of Patent Appeals and Interferences ("the Board") in response to the Examiner's Answer mailed on March 25, 2004. The Reply Brief is due on May 25, 2004. This Reply Brief is therefore timely submitted, and Appellants believe no fees are due in connection with this Reply Brief. However, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason related to this communication, the Commissioner is authorized to charge any underpayment or credit any overpayment to Lexicon Genetics Incorporated Deposit Account No. 50-0892.

I. REAL PARTY IN INTEREST

Appellants agree with the Examiner's assertion that "(a) statement identifying the real party in interest is contained in the brief" (Examiner's Answer at page 2).

II. RELATED APPEALS AND INTERFERENCES

Appellants agree with the Examiner's assertion that "(a) statement identifying the related appeals and interferences which (*sic*) will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief" (Examiner's Answer at page 2).

III. STATUS OF THE CLAIMS

Appellants agree with the Examiner's assertion that "(t)he statement of the status of the claims contained in the brief is correct" (Examiner's Answer at page 2).

IV. STATUS OF THE AMENDMENTS

Appellants agree with the Examiner's assertion that "(t)he appellant's (*sic*) statement of the status of amendments after final rejection contained in the brief is correct" (Examiner's Answer at page 2).

V. SUMMARY OF THE INVENTION

Appellants disagree with the Examiner's assertion that "(t)he summary of invention contained in the brief is deficient because the human polynucleotide and human G protein-coupled receptor that are the subjects of the instant invention are not 'novel'" (Examiner's Answer at page 2), allegedly because "(t)he novel aspect of the instant invention is the provision of an 'isolated' nucleic acid encoding the naturally occurring protein that is described in the instant specification" (Examiner's Answer at page 2). Appellants respectfully point out that the claimed invention is in fact directed to "(a)n isolated nucleic acid molecule" (see claim 1), and therefore stand behind the assertion as set forth in the Appeal Brief that "(t)he present invention relates to Appellants' discovery and identification of novel human polynucleotide sequences that encode a novel G protein-coupled receptor that spans the cellular membrane and is involved in signal transduction after ligand binding, and that has structural motifs found in the seven transmembrane domain (7TM) receptor family (specification at page 2, lines 9-13, and at page 4, lines 20-23)" (see the Appeal Brief at page 3). As the presently claimed invention is directed to what the Examiner himself acknowledges is the "novel aspect of the instant invention", and as no art rejections are currently entered against the pending claims, the Examiner's argument that the summary of the invention as set forth by Appellants in the Appeal Brief is "deficient" is completely without merit.

VI. ISSUES ON APPEAL

Appellants agree with the Examiner's assertion that "(t)he appellant's (*sic*) statement of the issues in the brief is correct" (Examiner's Answer at page 2).

VII. GROUPING OF THE CLAIMS

While Appellants agree with the Examiner's assertion that "(t)he rejection of claims 1 to 5 stand or fall together" (the Examiner's Answer at page 3), Appellants respectfully note for the record that the reason that "appellant's (*sic*) brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof" (the Examiner's Answer at page 3) is because the Appeal Brief included a **direct statement** by Appellants that "the claims will stand or fall together" (see the Appeal

Brief at page 3). Therefore, "appellant's (*sic*) brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof" (the Examiner's Answer at page 3) because it is **not Appellants' position that the claims do not stand or fall together**.

VIII. CLAIMS APPEALED

Appellants agree with the Examiner's assertion that "(t)he copy of the appealed claims contained in the Appendix to the brief is correct" (Examiner's Answer at page 3).

IX. PRIOR ART OF RECORD

Appellants agree with the Examiner's assertion that "(n)o prior art is relied upon by the examiner in the rejection of the claims under appeal" (Examiner's Answer at page 3).

X. ARGUMENT

A. Do Claims 1-5 Lack a Patentable Utility?

Appellants do not wish to restate all of the arguments presented in the Appeal Brief concerning the Examiner's allegation that claims 1-5 lack a patentable utility, and instead incorporate the entirety of Section VIII(A) of the Appeal Brief at this point herein by reference. However, Appellants are compelled to specifically address certain arguments presented in the Examiner's Answer for the record.

Appellants pointed out both in the Appeal Brief that the present nucleic acid sequences have utility in diagnostic assays, such as forensic analysis, as described in the specification as originally filed (see, for example, the specification at page 14, lines 5-8). As described in the specification on page 7, lines 21-30, the present sequences define two coding single nucleotide polymorphisms - specifically, a T/G polymorphism at position 233 of SEQ ID NO:1, which can lead to a valine or glycine residue at amino acid position 78 of SEQ ID NO:2, and a C/T polymorphism at position 316 of SEQ ID NO:1, which can lead to an arginine or cysteine residue at amino acid position 106 of SEQ ID NO:2. Appellants pointed out that as such polymorphisms are the basis for **forensic** analysis, which does not require any information at all about the ultimate biological function of the encoded protein, and that is undoubtedly a "real world" utility,

the presently claimed sequence must in itself be useful.

The Examiner argues that this utility "is not a specific and substantial utility", because "almost any cDNA can be employed as a forensic marker in some capacity" (the Examiner's Answer at page 7). The Examiner states that "(f)orensic markers in general, however, are only useful in the identification of the individual from which a sample originated through DNA fingerprinting, and provides no useful information about that individual beyond identification" (the Examiner's Answer at page 7). Appellants respectfully point out that "identification of the individual" is **exactly** the utility of forensic analysis as set forth by Appellants, specifically, the use of forensic analysis to distinguish **an individual** from **other individuals**, based solely on the **presence** or **absence** of one or more of the described polymorphisms. Appellants respectfully point out that this is one way in which polymorphic markers such as the presently described polymorphisms have been used for **decades** in forensic analysis. Therefore, this is clearly a well established technique, and as such, specific guidance does not need to be provided in the present specification, for it has long been established that a patent need not disclose what is well known in the art (*In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988)). Thus, the Examiner's argument does not support the allegation that the presently claimed invention lacks a patentable utility.

The Examiner further questions this asserted utility because there is no "precise information about the individual from which a sample under analysis was taken" (the Examiner's Answer at page 7). Appellants point out that this arguments has absolutely no bearing on the assertion that the polymorphisms described by Appellants can be used in **forensic** analysis. As detailed above, forensic analysis merely determines the presence or absence of one or more particular polymorphic markers as a means of distinguishing between individuals. As such, forensic analysis requires **absolutely no information whatsoever** about "information about the individual from which a sample under analysis was taken". Thus, the Examiner's argument once again in no way supports the allegation that the present claims lack a patentable utility.

With regard to the Examiner's argument that the use of polymorphic markers such as those described by Appellants in forensic analysis is not a "substantial" utility, Appellants hardly know where to begin. Naturally occurring genetic polymorphisms such as those described in the specification as originally

filed are both the basis of, and critical to, *inter alia*, forensic genetic analysis intended to resolve issues of, for example, identity or paternity. Forensic analysis based on polymorphisms such as those identified by Appellants is used to positively identify or rule out suspects in many criminal cases, and in identifying human remains. Paternity determination is based on polymorphisms such as those identified by Appellants to positively identify or rule out individuals suspected of fathering a particular child. Therefore, Appellants find the Examiner's position particularly difficult to comprehend. What could be possibly be more substantial and real world than the loss of an individual's freedom or life through incarceration? What could be possibly be more substantial and real world than the positive identification of human remains? What could be possibly be more substantial and real world than the impact, both economic and emotional, that the results of a paternity analysis has on the individuals directly and indirectly involved? These are all well known and generally accepted uses of polymorphisms such as the polymorphisms identified by Appellants. Without such identified polymorphisms, the skilled artisan would not be able to carry out such forensic or paternal analyses. Thus, the Examiner's allegations that the presently described polymorphisms are not "mature" and could not be "readily used in a real world sense" are completely without merit, and in no way whatsoever support the allegation that the presently claimed sequence lacks a patentable utility.

The Examiner further questions this asserted utility, stating "almost any cDNA can be employed as a forensic marker in some capacity" (the Examiner's Answer at page 7). Appellants reiterate that this argument is flawed in a **number** of respects. First, until a polymorphic marker is actually described it cannot be used in forensic analysis. Put another way, simply because there is a likelihood, even a significant likelihood, that a particular nucleic acid sequence will contain a polymorphism and thus be useful in forensic analysis, until such a polymorphism is actually identified and described, such a likelihood is **meaningless**. The Examiner appears to be attempting to use the information presented for the first time by Appellants in the instant specification as hindsight verification that the presently claimed sequence would be expected to have polymorphic markers. Such hindsight analysis based on Appellants discovery is completely improper. Second, the Examiner is clearly confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, which is clearly an improper standard. The fact that other polymorphic markers have been identified in other genetic loci does not mean

that use of the polymorphic markers identified by Appellants' in SEQ ID NO:6 in forensic analysis is not a specific utility. As clearly stated by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991; "*Carl Zeiss*"):

> An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Following directly from the quote above, an invention does not need to be the **only way** to accomplish a certain result. Thus, the question of whether or not other nucleic acid sequences contain polymorphic markers and can thus be used in forensic analysis is **completely irrelevant** to the present utility inquiry. The **only** relevant question in regard to meeting the standards of 35 U.S.C. § 101 is whether **every** nucleic acid can be so used - and the clear answer to this question is an emphatic **no**. Importantly, the holding in the *Carl Zeiss* case is **mandatory legal authority** that essentially controls the outcome of the present case. This case, and particularly the cited quote, **directly** rebuts the Examiner's argument.

Once again, the Examiner merely rehashes the standard irrelevant arguments concerning general utility - "that any purified compound having a known structure could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromotography (HPLC) and gas chromotography", and that "any item having a constant mass within an acceptable range can be employed to calibrate a produce scale in a grocery store" (the Examiner's Answer at page 8). Appellants have repeatedly pointed out that these staid and misplaced arguments are flawed in a number of critical respects. Appellants respectfully point out that the "general" class to which the Examiner refers is **all** nucleic acids. Appellants reiterate that **not all nucleic acids contain polymorphisms**. Therefore, the question of whether the asserted utility is "specific" instead of a general utility has **clearly** been laid to rest. The Examiner **repeatedly**, throughout the Examiner's Answer, alleges that he is not confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, but then consistently attempts to **narrowly** define the "general" class of the invention to include **only** those members that share the asserted utility, and

then allege that the asserted utility is a "general" utility. This is clearly evidenced by the Examiner's own statement that "**almost** any cDNA can be employed as a forensic marker" (the Examiner's Answer at page 7, emphasis added). Appellants respectfully point out that the "general" class of nucleic acids **cannot** be redefined to include **only** those nucleic acids that contain polymorphic markers, as the Examiner is forced to do in order to support the allegation that the claimed nucleic acids lack a patentable utility. Furthermore, another reason that such utilities as those listed by the Examiner are not specific is because these general utilities are applicable to a large number of **unrelated** compositions. Use as a calibration standard for a "produce scale" is a utility that is applicable to any composition, no matter how unrelated, that has mass. In other words, a metal block, an automobile, an elephant, or a nucleic acid molecule containing a polymorphism could be used to calibrate a produce scale, which is why use as a calibration standard for a produce scale is not a specific utility. However, a metal block, an automobile, or an elephant cannot be used in human forensic analysis. In fact, only nucleic acids, and specifically those human nucleic acids that contain a defined polymorphic marker, can be so used. Thus, this argument once again fails to support the Examiner's position.

The Examiner seems to discount the *Carl Zeiss* case cited by Appellants, stating that "(t)his decision is absolutely silent on the utility requirements for proteins, nucleic acids or chemical compounds and compositions in general" (the Examiner's Answer at page 10). Appellants reiterate that the holding in the *Carl Zeiss* case is **mandatory legal authority**, and that the Examiner **must** follow the precedent as applied to the broad issue at hand in the *Carl Zeiss* case, unless this case has been specifically limited to it's facts by the **Court itself**. Appellants are unaware of **any** such holding, and the Examiner has cited **no** such holding. Furthermore, Section 101 of the Patent Act of 1952, 35 U.S.C. § 101, provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may obtain a patent on the invention or discovery. Appellants point out that 35 U.S.C. § 101 covers devices (machines) as well as compositions, and makes no distinction between the two with regard to meeting the burden of complying with 35 U.S.C. § 101. Thus, this argument is completely improper, and totally fails to support the alleged lack of utility of the presently claimed compositions.

Furthermore, Appellants note that the Examiner repeatedly cites the need for "further characterization" (the Examiner's Answer at page 4), "further experimentation" (the Examiner's Answer at page 11), or "further research" (the Examiner's Answer at page 6) throughout the Examiner's Answer to support the allegation that the present invention lacks a patentable utility. Appellants reiterate that the standard for meeting the requirements of 35 U.S.C. § 101 is not whether "further characterization", "further experimentation", or "further research" is required to practice certain aspects of the claimed invention, but whether **undue** experimentation would be required to practice the claimed invention. The widespread use of polymorphisms such as those described by Appellants in forensic analysis every day **strongly** argues against such a use requiring "undue experimentation". In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (CCPA 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands, supra.* Thus, the Examiner's argument does not support the alleged lack of utility, and the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Examiner further states that "Appellant does not identify any reference of record that describes 'a family of polymorphisms that have a well established utility'" (the Examiner's Answer at page 10). This statement is completely contradicted by the Examiner's own statement that "(i)t is well known in the art of molecular biology that the nucleotides sequences encoding an amino acid sequence of any particular protein will have inconsequential differences from individual to individual, as will the amino acid sequences encoded thereby ... (t)his is why all humans are not all identical and why DNA fingerprinting works" (the Examiner's Answer at page 7). Thus, Appellants reliance on the holding in *In re Brana,* (34 USPQ2d 1436 (Fed. Cir. 1995)) is not at all "misplaced" (the Examiner's Answer at page 11). Appellants respectfully point out for the record that the Examiner has provided absolutely **no** evidence of record that would serve to show that an artisan skilled in the art of forensic analysis would doubt Appellants asserted utility. As set forth by

Appellants in the Appeal Brief, it has been clearly established that a statement of utility in a specification must be accepted absent reasons why one skilled in the art would have reason to doubt the objective truth of such statement. *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA, 1974; "*Langer*"); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA, 1971). As set forth in *In re Langer* (183 USPQ 288 (CCPA 1974); "*Langer*"):

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Langer at 297, emphasis in original. As set forth in the MPEP, "Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered 'false' by a person of ordinary skill in the art" (MPEP, Eighth Edition at 2100-40, emphasis added). Thus, absent such **evidence** from the Examiner concerning the use of the presently described polymorphisms in forensic analysis, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Additionally, in the Appeal Brief, Appellants pointed out that two sequences sharing 100% percent identity at the protein level over the entire length of the claimed sequence is present in the leading scientific repository for biological sequence data (GenBank), and has been annotated by third party scientists *wholly unaffiliated with Appellants* as "Homo sapiens similar to olfactory receptor MOR40-13" (see **Exhibits A** and **B** of the Appeal Brief). Furthermore, the murine olfactory receptor sequence referred to above (MOR40-13) shares over 84% percent identity at the protein level and 91% similarity at the protein level with the claimed sequence (see **Exhibit C** of the Appeal Brief). As set forth repeatedly by Appellants, the legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. Given this GenBank annotation, there can be no question that those skilled in the art would clearly believe that Appellants' sequence is an olfactory receptor protein, which is clearly involved in chemical communication, exactly as asserted by Appellants in the specification as originally filed (at least at page 1, line 28). Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Examiner once again questions this asserted utility, stating that "the simple description of a

chemical compound in a public forum does not automatically convey upon that compound a specific and substantial utility" (the Examiner's Answer at page 12). Appellants respectfully point out that the GenBank records cited by Appellants were not cited merely to show "the simple description of a chemical compound in a public forum", but, rather, to evidence the high degree of homology between the presently claimed sequence and sequences that have been functionally characterized. Appellants respectfully point out that the **USPTO itself** clearly recognizes the assignment of function based on homology. Example 10 of the Revised Interim Utility Guidelines Training Materials (see **Exhibit D** of the Appeal Brief) only requires a similarity score greater than 95% to establish functional homology, without **any** direct demonstration of function. Thus, the Examiner's argument once again does not support the allegation that the presently claimed sequence lacks utility.

Furthermore, Appellants detailed additional examples of the utility of the present nucleotide sequences, such as in assessing gene expression patterns using high-throughput DNA chips. The Examiner continues to question these assertions of utility, because "this is a utility which (*sic*) would apply to virtually ever (*sic*) member of a general class of materials, such as any collection of proteins or DNA" (the Examiner's Answer at page 15). Appellants wish to emphasize that the Examiner is once again clearly confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, which is clearly an **improper** standard (*Carl Zeiss, supra*). Once again, the "general class" to which the Examiner refers is **all** nucleic acids. Appellants reiterate that **not all nucleic acids are expressed**, and therefore able to be used to monitor gene **expression** patterns using DNA chips. Appellants pointed out in the Appeal Brief that only a minor percentage (2-4%) of the genome actually encodes exons, which in-turn encode amino acid sequences. Once again, the Examiner is attempting to **narrowly** define the "general class" of all nucleic acids to include **only** those members that share the asserted utility, in this case "all cDNAs encoding proteins of human origin", and then assert that the asserted utility applies to a "general class". Appellants reiterate that the "general class" of all nucleic acids **cannot** be redefined to include **only** those nucleic acids that are expressed, as the Examiner is forced to do in order to support the allegation that the claimed nucleic acids lack a patentable utility. Therefore the present claims are clearly in compliance with 35 U.S.C. § 101.

The Examiner further questions the utility of the presently claimed sequences, stating that "there is no evidence of record that any odorant receptor is the target of a specific therapeutic compound or has been shown to be associated with a particular disease or disorder" (the Examiner's Answer at page 15). Appellants respectfully point out that neither the identification of "a specific therapeutic compound" that interacts with the claimed sequence, nor the association of a particular nucleotide sequence with a "particular disease or disorder" is **not** the standard for patentability under 35 U.S.C. § 101 (*In re Brana, supra*). Therefore, once again, the the Examiner's argument does not support the alleged lack of utility.

Finally, Appellants pointed out in the Appeal Brief that a number of patents have been issued over the years that claim nucleic acid fragments that do not comply with the new Utility Guidelines, and that holding Appellants to a different standard of utility would be arbitrary and capricious, and, like other clear violations of due process, cannot stand. The Examiner states that "(t)hose guidelines were most certainly formulated with full knowledge of all judicial precedents applicable thereto" (the Examiner's Answer at page 10). Appellants respectfully point out that any guidelines set forth by the USPTO should not be confused in **any way** with the force of law. For example, *In re Brana, supra*, is just one example of the Federal Circuit overturning guidelines enacted *sua sponte* by the USPTO.

For each of the foregoing reasons, as well as the reasons set forth in the Appeal Brief, Appellants submit that the rejection of claims 1-5 under 35 U.S.C. § 101 must be overruled.

B. Are Claims 1-5 Unusable Due to a Lack of Patentable Utility?

Regarding the rejection of claims 1-5 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by either a clear asserted utility or a well-established utility, Appellants submit that as claims 1-5 have been shown to have "a specific, substantial, and credible utility", as detailed in Section X(A) above, as well as Section VIII(A) of the Appeal Brief, the present rejection of claims 1-5 under 35 U.S.C. § 112, first paragraph, cannot stand.

Appellants therefore submit that the rejection of claims 1-5 under 35 U.S.C. § 112, first paragraph, must be overruled.

XI. CONCLUSION

Appellants respectfully submit that, in light of the foregoing arguments, the Final Action's conclusion that claims 1-5 lack a patentable utility and are unusable by the skilled artisan due to a lack of patentable utility is unwarranted. It is therefore requested that the Board overturn the Final Action's rejections.

Respectfully submitted,

May 25, 2004
Date

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TABLE OF AUTHORITIES

CASES

STATUTES